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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,661	02/28/2002	Masatoshi Chiba	P21749	5687
7055 7590 08/11/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER KOLKER, DANIEL E				
ART UNIT		PAPER NUMBER		
1649				
NOTIFICATION DATE		DELIVERY MODE		
08/11/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 09/926,661	<b>Applicant(s)</b> CHIBA, MASATOSHI
<b>Examiner</b> DANIEL KOLKER	<b>Art Unit</b> 1649

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 31 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 3, 4 and 6-16.  
Claim(s) withdrawn from consideration: 22-28.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Daniel E. Kolker/  
Primary Examiner, Art Unit 1649  
August 7, 2009

Continuation of 11, does NOT place the application in condition for allowance because: No claims were amended. Applicant presented arguments as to why the claimed invention is patentable over Tanaka in view of Yamahira. Applicant argued that Yamahira teaches the stabilizing effects are specific to urokinase, and therefore would not be expected to be applicable to other proteins. This argument is not persuasive. At column 1 lines 57-63, the section cited by applicant on p. 4 of the remarks filed 31 July 2009, Yamahira teaches that the stabilizing effect is specific to "polar" amino acids, and cannot be extended to non-polar amino acids. The specificity of the stabilizing effect has to do with the amino acid selected, not the protein to be stabilized. Applicant also argues that the product-by-process claims are patentable over the combined references. Applicant argues that the preparations made from solutions with HGF at less than 5 mg/ml are materially different from those made at higher concentrations, when a stabilizer is included. This argument is not persuasive. Table 8 on p. 25 of the specification shows that including glycine as a stabilizer decreases aggregates from 11.24 to 9.58 (14.7%) for a solution at 1 mg/ml of HGF. However, including glycine in the 20 mg/ml solution results in decreasing aggregates from 6.17 to 4.09, a 33.7% decrease in aggregate formation. Similar results were obtained with alanine. It may be the case that adding glycine or alanine is more effective at decreasing aggregates in the 20 mg/ml solution than in the 1 mg/ml solution. However, applicant is not claiming a method of decreasing aggregate formation, applicant is claiming a lyophilized preparation of HGF. The evidence set forth in the specification does not indicate that the product, lyophilized HGF, is materially different when the concentration prior to lyophilization is manipulated. Therefore recitation of product-by-process limitations fails to render the claims patentable. Furthermore it is noted that the evidence presented at Table 8 and referred to in the arguments of 31 July 2009 is not commensurate in scope with the present claims, as data from only 2 amino acids are provided.

For at least the reasons above, and those previously made of record, the rejections of record stand. No claim is allowed.